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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

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| EXAMINER |
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MCEVOY, THOMAS M

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| ART UNIT | PAPER NUMBER |
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3731

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09/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/557,515 | Applicant(s) FUKUZAWA ET AL. | |
| | Examiner THOMAS MCEVOY | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 11-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10 and 24 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Examiner does not see where an elastic member at the end of a groove of the first or second moving member impacts the second moving member during the retreating movement of the second moving member.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is structurally claimed since it appears that there is no elastic member at the end of a groove of the first or second moving member which impacts the second moving member during the retreating movement of the second moving member.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Garthe et al. (DE 102 06 254 using US 2003/0225429 as the English equivalent).

Regarding claim 1, Garthe et al. disclose a lancing device comprising: a first moving member, 40 or 51 or 40/51, holding a lancing member moved from a standby position to a puncturing position in a puncturing direction for puncturing a target portion by the lancing member; a second moving member 60 or 60/61 connected to the first moving member, for controlling the movement of the first moving member; a housing 11 for accommodating the first and the second moving members, while allowing the movement of the moving members; a movement converting mechanism 61/52/53 (a mechanism can comprise already claimed structural components; Examiner notes that Applicant's mechanism requires the grooves of the first and second moving members to function) for converting retreating movement of the second moving member away from the puncturing position into advancing movement of the lancing member to the puncturing position; and an impact absorbing means 53', connected to the housing, that

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comes into stopping contact with the second moving member in the retreating movement for absorbing impact that is caused when the first and the second moving members come to stop on puncture operation.

7. Claims 1-4, 6, 7, 9 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitson et al. (US 7,144,404 B2).

Regarding claims 1-3 and 6, Whitson et al. disclose a lancing device comprising: a first moving member 22/24 holding a lancing member moved from a standby position (position 4, Figure 7) to a puncturing position (position 1, Figure 7; a position ready to initiate puncturing, etc.; the claim term is not well defined) in a puncturing direction (in moving from 4 to 1, the first moving member moves in a direction towards a final puncturing position) for puncturing a target portion by the lancing member; a second moving member 12 connected to the first moving member, for controlling the movement of the first moving member; a housing 240/242 for accommodating the first and the second moving members while allowing the movement of the moving members; a movement converting mechanism for converting retreating movement of the second moving member away from the puncturing position into advancing movement of the lancing member to the puncturing position (evident from Figures 6 and 7; note horizontal line of cross-hairs in Figure 7 demarking a longitudinal position of the first moving member; note that second moving member is retreating from positions 3 to 4 to 1); and an elastically deforming impact absorbing means 28 that comes into stopping contact with the second moving member in the retreating movement (spring 28 is biased in puncturing direction so it must provide resistance to stop or assist in stopping

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member 12; Examiner notes that this recoil portion of the retreating movement in this application and the prior art does not result in opposite movement of the first moving member), connected to the housing (via member 90) for absorbing impact that is caused when the first and the second moving members come to stop on puncture operation. Regarding claim 4, the housing is provided with a projection 90 for fixing the elastic member, the elastic member being a ring (series of rings) fitting around the projection. Regarding claim 7, member 90 can be considered as an operating portion and it connects to members 288/289 through an open end of the housing. Regarding claim 9, the movement converting mechanism comprises a link 16 connecting the first and second moving members and the second moving member 12 has grooves which allow the shaft of the link to rotate and therefore move. Regarding claim 24, reciprocal (up and down) movement of the second moving member (positions 1 to 2 to 3 to 4 to 1, Figure 7) is transformed into reciprocal movement of the first moving member (see comments for claim 1).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2, 3, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe et al. (DE 102 06 254 using US 2003/0225429 as the English equivalent) in view of Alden et al. (US 7,033,371 B2) and Stanton (US 2,993,698).

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Regarding claims 2 and 3, Garthe et al. fail to disclose an elastically deforming impact absorbing means as claimed. Alden et al. teach that mechanical stops in a lancet (such as the groove of Garthe et al.) can cause vibration and excess pain to a patient (col. 2, lines 32-49; col. 3, lines 9-15). Stanton discloses that a vibration transferred to a link in a groove (similar to the link and groove of Garthe et al.) can be minimized by lining the groove with rubber (col. 3, lines 1-11 and elsewhere). It would have been obvious to one of ordinary skill in the art to have minimized vibrations caused by the mechanical stops (groove sections) of the Garthe et al. device as taught by Alden et al. It would have been obvious to one of ordinary skill in the art to have used rubber lining within the groove to dampen the vibrations as taught by Stanton. Regarding claim 9, the movement converting mechanism comprises a link 61 connecting the first and the second moving members for moving the first moving member upon the movement of the second moving member, wherein the first moving member is formed with a groove for allowing movement of a shaft of the link (Figures 4A-C). Regarding claim 10, the elastic member would be provided at upper and lower ends of the groove.

10. Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitson et al. (US 7,144,404 B2) in view of Alden et al. (US 7,033,371 B2) and Tone (US 4,328,879).

Regarding claims 5 and 10, Whitson et al. disclose the device as described above but fail to disclose an elastic support in the groove. Alden et al. teach that mechanical stops in a lancet (such as the grooves of member 12 of Whitson et al.; especially at the impact points 1-4) can cause vibration and excess pain to a patient

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(col. 2, lines 32-49; col. 3, lines 9-15). Tone teaches that it is known in a variety of arts to line a variety of gear drives with rubber in order to minimize shock and vibration (col. 1, lines 14-29). It would have been obvious to one of ordinary skill in the art to have minimized vibrations caused by the mechanical stops (grooves and corners of member 12) of the Whitson et al. device as taught by Alden et al. It would have been obvious to one of ordinary skill in the art to have used rubber lining within the parallelogram of member 12 or around gear 16 to dampen the vibrations as taught by Tone.

Response to Arguments

11. Applicant's arguments filed June 2nd 2009 have been fully considered but they are not persuasive. Applicant has argued on p. 7 that member 60 of Garthe et al. remains [longitudinally] stationary during the puncturing process. Examiner respectfully disagrees and believes that Garthe et al. disclose and clearly draw that there is some slight rearward migration of member 60 during the puncturing process (col. 6, lines 45-50; Figures 4A-4C). Applicant has argued that Garthe et al. fail to disclose the claimed movement converting mechanism. Examiner believes that the mechanism of Garthe et al. requires retreating movement of the second moving member for the claimed movement of the first moving member. Applicant has argued that Whitson et al. do not disclose the claimed movement converting mechanism. Examiner has addressed in greater detail above how Whitson et al. is believed to disclose this claimed mechanism.

Allowable Subject Matter

12. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas Mcevoy/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
8/29/09